

Defendant.

Civil Action No. _____

2/ EGFR is present in at least 70% of human cancers, and is therefore widely recognized as a promising target for the design and development of compounds that can serve as either diagnostic or therapeutic agents.

It operates extensive cancer research laboratories and provides treatment for cancer patients from all over the world and is affiliated with Harvard University School of Medicine.

3. Gatekeeper Pharmaceuticals, Inc. is a Delaware corporation with a principal place of business at 1170 Tuolumne Court, Millbrae, California 94030-1554. On information and belief, Gatekeeper was formed in 2009 primarily to develop WZ4002.

JURISDICTION AND VENUE

4. This Court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 2201 and 2202 on the basis that Dana-Farber seeks declaratory relief with respect to an actual controversy that exists between the parties to this action.

5. This Court has jurisdiction over this parties pursuant to 28 U.S.C. § 1332(a) as the matter concerns citizens of different states and the controversy exceeds the sum or value of \$75,000.

6. This Court possesses personal jurisdiction over the defendant pursuant to G.L. c. 223A, §3 on the basis that the defendant has conducted business in, and has maintained the necessary contacts with, the Commonwealth of Massachusetts to permit the exercise of jurisdiction over the defendant with respect to this action.

7. Venue is proper in this judicial district 28 U.S.C. § 1391 on the basis that Dana-Farber resides in this district and because a substantial part of the acts giving rise to this claim occurred in this district.

FACTS

Dana-Farber's Collaborative Research Agreement with Novartis

8. On January 1, 2005, Dana-Farber and Novartis International Pharmaceutical Ltd. ("Novartis") entered into a Collaborative Research Agreement (the "Novartis CRA"), under

which Dana-Farber and Novartis agreed to collaborate for the purpose of “mobil[izing] the skills, knowledge and experience developed at [Dana-Farber] ... for a focused and coordinated attack on ... cancer with the goal of producing new anti-cancer agents.” Novartis CRA, ¶ 2.

9. Under the Novartis CRA, in return for certain funding provided to Dana-Farber for approved research projects, Novartis is entitled to an exclusive or nonexclusive license, at its election, to “Program Intellectual Property.” Novartis CRA, ¶ 19.2.

10. “Program Intellectual Property” is defined to be “all proprietary rights in Program Technology,” which is defined to include:

“technology invented, discovered or developed in whole or in part by an Institute Program participant, which is conceived or reduced to practice *as part of a Funded Research Project . . . or by using the funds provided by Novartis for a Funded Research Project . . .*” (emphasis added).

Novartis CRA, ¶ 1.

11. “Funded Research Project(s)” is in turn defined in the Novartis CRA as:

“research project(s) under the direction of an Institute scientist based upon a grant proposal that was submitted to and which was accepted ... for funding pursuant to this Agreement.”

Novartis CRA, ¶ 1.

The WZ4002 Invention

12. WZ4002 was discovered through a collaboration of four Dana-Farber scientists and their laboratories. Two of these scientists, Dr. Nathanael Gray (“Dr. Gray”) and Dr. Michael Eck (“Dr. Eck”), applied for, received and ultimately directed “Funded Research Projects” under the Novartis CRA during the time period relevant to the WZ4002 invention. Dr. Gray and Dr. Eck at all relevant times were full time employees of Dana-Farber.

The Gatekeeper Option Agreement

13. In the spring of 2009, Dr. Gray initiated a proposal for Dana-Farber to enter an Option Agreement for license rights to WZ4002 with a newly created entity, Gatekeeper Pharmaceuticals, Inc. (“Gatekeeper”), of which Dr. Gray was a founder and shareholder.

14. On the basis of representations made by Dr. Gray concerning the work and funding involved in the WZ4002 discovery, Dana-Farber concluded that the WZ4002 discovery was not subject to the Novartis license rights under the Novartis CRA and entered into an Option Agreement for WZ4002 with Gatekeeper on June 1, 2009 (the “Gatekeeper Option Agreement”).

15. Under the Gatekeeper Option Agreement, Dana-Farber granted Gatekeeper an exclusive option to enter into an exclusive license to the patent rights under Dana-Farber’s WZ4002 patent application. Gatekeeper Option Agreement, Section 2.1.

16. The Gatekeeper Option Agreement provides that Gatekeeper may exercise the Option within a 12 month period upon demonstrating that it had received at least two hundred and fifty thousand dollars of financing. Gatekeeper Option Agreement, Section 3.2.

17. The Gatekeeper Option Agreement provides that if Gatekeeper exercises the Option during the Option Period, Dana-Farber and Gatekeeper are to “negotiate diligently and in good faith” to agree upon a definitive license agreement. Gatekeeper Option Agreement, Section 3.3.

18. The Gatekeeper Option Agreement also provides that it shall terminate “and the parties shall have no further obligation” if, “despite good faith efforts” the parties have not succeeded in their negotiations and executed a license agreement within 180 days of Gatekeeper’s exercise of the option. Gatekeeper Option Agreement, Section 3.5.

19. The Gatekeeper Option Agreement provides that it “shall be construed and the rights of the parties determined by the laws of the Commonwealth of Massachusetts.”

Gatekeeper Option Agreement, Section 6.4

Novartis’ Assertion of Rights to an Option on WZ4002

20. On information and belief, Novartis learned of the WZ4002 invention in the fall of 2009 upon receiving an article about WZ4002 written for the scientific journal *Nature* by Dr. Gray and the other WZ4002 collaborators.

21. In October 2009, Dana-Farber learned that Novartis was asserting a right to a license to the WZ4002 intellectual property. On information and belief, the ground for Novartis’ assertion of rights to WZ4002 was – and continues to be – Novartis’ belief that the WZ4002 invention constitutes “Program Intellectual Property” and that it falls within the “Funded Research Projects” directed by Dr. Gray and/or Dr. Eck under the Novartis CRA.

22. On November 24, 2009, Novartis gave notice to Dana-Farber that it believed Dana-Farber had breached the Novartis CRA by failing to report the WZ4002 discovery to Novartis, enabling its option to obtain a license, and by entering into the Gatekeeper Option Agreement.

Gatekeeper Seeks To Exercise Its Option on a License to WZ4002

23. In the spring of 2010, Gatekeeper sent a notice to DFCI seeking to exercise its option to an exclusive license on WZ4002.

24. On April 23, 2010, Gatekeeper sent a notice to Dana-Farber reporting that it had obtained the requisite financing and was exercising its option to negotiate a license to WZ4002.

25. At that time, Gatekeeper also sent a draft license agreement to Dana-Farber. The draft license agreement proposed by Gatekeeper contained the recital that “DFCI is the owner of

[the intellectual property covered by the WZ4002 patent application] *subject only to a royalty-free, nonexclusive license previously granted to the United States government*” (emphasis added).

26. Section 10.1 of the draft license also contained a representation and warranty of Dana-Farber that it:

“has the right and authority to enter into this Agreement and grant the rights and licenses hereunder.”

Dana-Farber Determines It Cannot Grant WZ4002 License Rights to Gatekeeper

27. Faced with the conflicting claims of Novartis and Gatekeeper to license options to WZ4002, Dana-Farber sought to determine whether some compromise solution could be reached among Dana-Farber, Novartis and Gatekeeper.

28. When it became apparent that a compromise agreeable to both Novartis and Gatekeeper would not be forthcoming, Dana-Farber undertook an internal review of the background of the WZ4002 discovery to determine the correctness of its earlier conclusion that it was able to grant the WZ4002 to Gatekeeper.

29. In August 2010, Dana-Farber completed this review and concluded that Novartis had a strong claim to the option under the Novartis CRA and therefore, that Dana-Farber did not have the capacity to grant the WZ4002 license requested by Gatekeeper under the Gatekeeper Option Agreement. On August 30, 2010, Dana-Farber notified Gatekeeper accordingly.

30. On information and belief, Gatekeeper continues to assert that Dana-Farber is obliged to grant it an exclusive license to WZ4002 pursuant to the Gatekeeper Option Agreement.

COUNT I
(Declaratory Judgment)

1. Dana-Farber repeats and realleges the allegations contained in paragraphs 1 to 30 as if set forth fully herein.

2. An actual controversy exists between Dana-Farber and Gatekeeper regarding the obligations of Dana-Farber and the rights of Gatekeeper, if any, in connection with WZ4002 and the Gatekeeper Option Agreement.

WHEREFORE, Dana-Farber respectfully requests that the Court enter a declaratory judgment and enter an Order:

- (a) Declaring that Dana-Farber has complied with its obligations under the Gatekeeper Option Agreement, if any;
- (b) Declaring that Dana-Farber is excused from any further performance under the Gatekeeper Option Agreement; and
- (c) Granting such other relief as this Court may deem just and appropriate.

JURY DEMAND

Plaintiff demands a jury trial on all issues so triable.

Respectfully submitted,

**DANA-FARBER CANCER INSTITUTE,
INC.**

By its attorneys,

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